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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/09/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/096,593

Applicant(s)

O'CONNOR ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request For Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/13/02 has been entered.

Amendment Entry

2. Applicant's response to the Final Office Action mailed April 19, 2002 (Paper #25, filed 9/13/02) is acknowledged. In response to amendment-E filed therein claim 18 has been cancelled. Claims 1-17 and 20-29 are pending. Claims 1-17 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. (Paper #7 filed 11/9/99). Claims 20-29 are under consideration.

Amendment History

3. Several amendments have been entered in the instant application. The following serves to accurately indicate the pending claims:

I. Amendments Not Entered:

Supplemental Amendment (filed 3/21/02) – Claims not found allowable because of broad claim 30. The amendment was not entered as requested by Applicant (Silva).

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II. Amendments Entered:

Amendment A (Paper #7 filed 11/9/99) - Elected claims 18-19 added new claims 20-28.

Amendment B (Paper #12 filed 5/24/00) - No claim changes.

Amendment C (Paper #17 filed 4/3/01) – Claim 19 canceled, claims 20 and 22 amended, new claim 29 added.

Amendment D (Paper #21 filed 11/27/01) – No claim changes. New claim 30 not submitted properly, therein it was not entered. Claim 30 submitted in the appendix – not a correct amendment.

Amendment E (Paper #25 filed 9/13/02) – canceled claim 18.

OBJECTIONS WITHDRAWN

Drawings

4. The drawings filed on 1/10/01 (figures 7A-7S) are acceptable subject to correction of the informalities indicated on the attached “Notice of Draftsperson’s Patent Drawing Review,” PTO-948 attached. The drawings filed on 6/12/98 (figures 1-6E) are acceptable subject to correction of the informalities indicated on the attached “Notice of Draftsperson’s Patent Drawing Review,” PTO-948 attached to paper #8. *Applicants have filed formal drawing of figure 7A-7S and 1-6E therein obviating the objection. The objection is withdrawn.*

REJECTIONS WITHDRAWN

5. The prior art of record in paper #22 has been withdrawn in light of the Terminal Disclaimer of U.S. Patent #6,096,273 (Paper #27 filed 9/13/02) and the Declarations under 37 CFR 131 of O’Connor and Kayyem (Paper #26 filed 9/13/02). The declarations dating the conception of the instant invention to March 7, 1997 has been found persuasive.

NEW GROUNDS OF REJECTION

Claim Objections

6. Claims 21 and 24-28 are objected to under 37 CFR 1.75(c) as being in improper form because they depend on cancelled claim 18. Claim 18 should be removed from the claims in order to obviate this rejection. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

I. Claims 20 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Ribí et al. (U.S. Patent #5,571,568).

Ribí et al. disclose a bio-electronic sensor (apparatus) comprising a test chamber (Figure 1 #12 and #14) with an array of electrodes (figure 1 #16). The electrodes are configured or positioned to require at least one set of conducting electrodes (at least one second measuring electrode) separated by a space (figure 1 #18). See column 24 lines 9-18. Each electrode is coated (SAM) with receptors for an analyte of interest. In other words each electrode could be utilized to detect the same analyte or different analyte of interest. See figure 3 and column 24 lines 18-24. The sensor is linked to a voltage source (figure 5 #64) and an electronic detector (figure 5 #66 and #96).

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In one embodiment the substrate is coated with an electrically conductive polymer (spacer). The films are taught to be acceptable in self-assembled arrangements (Column 4 lines 16-20). Protein binding ligands which include are taught in column 7 line 30 through line 59.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribí et al. (U.S. Patent #5,571,568) in view of Kayyem et al. (U.S. Patent #6,221,583) and in further view of Kossovsky et al. (U.S. Patent #5,585,646).

Please see Ribí et al. as set forth above.

Ribí et al. differ from the instant invention in failing to specifically teaching self-assembled monolayer devices/apparatus including insulators and/or conductive oligomers.

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However, Kayyem et al. teach devices which include both insulators and conductive oligomers. Kayyem et al. further disclose that oligomers can exits in the apparatus as an insulator. See column 6 lines 24-57 and column 22 line 66 through column 24 line 42.

While, Kossovsky et al. disclose improved bioelectronics devices in comprising a layer of a polyhydroxy oligomer that is spaced between the surface of a semi conductive material (applicants monolayer) and a electronically active biochemical molecule (applicants binding ligand) which is bound to the semi conductive surface of an electronic device (applicants electrode). The layer of polyhydroxy oligomer functions as a biochemical stabilization layer to prevent denaturization of the electronically active biochemical molecule (Abstract). The stabilization layer is made up of one or more polyhydroxy oligomers. Exemplary polyhydroxy oligomers include carbohydrates, carbohydrate derivatives, and other macromolecules with carbohydrate like components. Kossovsky et al. further teach that the surface modification concept and the electron donor-acceptor concept can be combined at the semiconductor surface and utilized in various methods. Specifically cited is the method of Colvin et al.(Column 4, Lines 12-25). Colvin et al. Construct devices by attaching semiconductor nanocrystals to metal surfaces using self-assembled monolayers as bridging compounds.

Ribi et al. (U.S. Patent #5,571,568) in view of Kayyem et al. (U.S. Patent #6,221,583) and in further view of Kossovsky et al. (U.S.Patent#5,585,646) are analogous art because they are from the same field of endeavor, all three inventions teach the fabrication/utility of electrochemical biosensors.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the insulators and/or conductive oligomers taught by Kayyem et al. and Kossovsky et al. in the apparatus/device of Ribí et al. to perform analyte detection in an affinity assay system because Kayyem et al. taught that insulators serve to inhibit or slow electron transfer (column 24 lines 25-27) and conductive oligomers increase the rate of electron transfer and are more conductive than the insulators (column 6 lines 25-47). Further, Kossovsky et al. disclosed that the use of self assembled monolayers allows the molecules to be held in a specific orientation with respect to the metal and are applicable in many system designs (Column 4, Lines 12-25).

recent advances have extended self-assembled monolayers beyond the prototype gold/thiol systems. Fatty acids on aluminum, silanes on silicon, isonitriles on platinum and rigid phosphates on metals are all examples.

Kossovsky et al. also teach the use of the any denaturization of the biochemical material which might be caused by the semiconductor material is eliminated or substantially reduced by placing the stabilization layer of polyhydroxy oligomers between the biochemical material and the semiconductor (Column 7, Lines 13-18).

One of ordinary skill would have been motivated to employ insulators and or conductors (oligomer) to control electron transfer in binding systems like the one of Ribí et al. to ensure optimal working ranges for precise and accurate evaluation of an analyte of interest.

II. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ribí et al. (U.S. Patent #5,571,568) in view of Wohlstadter et al. (U.S. Patent #6,090,545).

Please see Ribí et al. as set forth above.

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Ribi et al. differ from the instant invention in failing to specifically teach a processor for data analysis in their device designs.

However, Wohlstadter et al. disclose patterned, multi-array multi-specific surfaces on a support (PMAMS) that are electronically excited in electrochemiluminescence (ECL) based tests. The PMAMS can be generated from self- assembled monolayers on a surface. (column 13, lines 10-31). In figure 47 shows an embodiment in which the multi-array apparatus/device includes a microprocessor/computer containing controller means for generating and analyzing ECL signals. See column 7 lines 38-40. The apparatus further provides a voltage source and photon detector. Column 3 lines 59-65 and column 22 Voltage Waveform.

Ribi et al. (U.S. Patent #5,571,568) and Wohlstadter et al. (U.S. Patent #6,090,545) are analogous art because they are from the same field of endeavor, both inventions teach the fabrication/utility of electrochemical biosensors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a processor/computer to analyze the generated device signals as taught by Wohlstadter et al. in the apparatus/device of Ribi et al. to perform analyte detection because Wohlstadter et al. indicate that “computer controlled voltage systems” are advantageous. Specifically the computer/processor can be used to select a particular electrical potential or a particular range of electrical potentials over a predetermined time. Column 24 line 63 to column 25 line 5.

One of ordinary skill would have been motivated to do this in order to control the device reaction parameters and produce accurate/reproducibly data analyses in rapid time.

Response to Arguments

9. Applicant's arguments filed 9/13/02 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to the reference of Keen, Applicant contends that the reference is not prior art because the declarations by inventors Kayyem and O'Connor indicate reduction to practice of the instant invention to May 14, 1997 via provisional application #60/040,153. Therein the Keen reference has been removed from the rejection. It is noted that the instant application does not claim benefit to provisional application #60/040,153.

Applicant argues that Kossovsky et al. do not teach the utility of bioelectronic devices for the detection of target analytes in biological samples. It is noted that analyte detection is taught in US Patent #5,571,568 to Ribic et al. US Patent #5,571,568 has been cited in combination with Kossovsky et al. and Wohlstadter et al. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

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In response to the argument that Wohlstadter et al. do not teach binding domain bound attached to the electrodes and detects the analytes based on electrochemiluminescence rather than electrochemical detection, it is noted that Wohlstadter et al. are cited with Ribi et al. Ribi et al. teach the instant electrode configuration, while Wohlstadter et al. are merely relied on for the inclusion of a processor/computer.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., electrochemiluminescence rather than electrochemical detection) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. For reasons aforementioned, no claims are allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook

Patent Examiner

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CM1 7B17

703-305-0808



LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/07/03